K093730

510(k) Summary

JAN 14 2010

Submitter:	Edwards Lifesciences Research Medical, Inc.
Contact Person:	Spencer Walker, Associate II, Regulatory Affairs 6864 South 300 West Midvale, UT 84047 801-565-6103
Date Prepared:	December 2, 2009
Trade Name:	PORT ACCESS Systems EndoDirect Arterial Cannula
Classification Name:	Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass 21 CFR Part 870.4210, Product Code DWF, Class II
Predicate Device:	Edwards Lifesciences DirectFlow Arterial Cannula

Device Description:
Edwards EndoDirect arterial cannula is a flexible plastic tube intended to provide a means of safely delivering oxygenated blood for cardiopulmonary bypass procedures and allows for the hemostatic introduction and removal of vascular catheters.

The EndoDirect arterial cannula has the following features: a beveled tip with an end hole, side perfusion holes, and a stabilizer ring for suture and tourniquet, a wirewound shaft for flexibility and kink resistance, a barbed connection site with 3/8 in. acceptance, a hemostasis valve, and a mark indicating tip orientation. A lubricious coating is applied to the surface of the cannula body to facilitate ease of insertion and retraction of the EndoClamp aortic catheter.

Intended Use:
EndoDirect Arterial Cannula
The EndoDirect arterial cannula is indicated for patients undergoing cardiopulmonary bypass. The cannula is intended to deliver oxygenated blood for cardiopulmonary bypass for a duration of less than 6 hours. The EndoDirect arterial cannula also allows the hemostatic introduction and removal of vascular catheters such as the Port Access EndoClamp aortic catheter. The EndoDirect arterial cannula is intended for introduction and use through a thoracic trocar or incision.

AutoIncisor Introducer: The AutoIncisor introducer is intended for use with Port Access arterial cannulae. It is intended for incising the aorta and introducing the cannula into the aorta.

Comparative Analysis:
It has been demonstrated that the proposed arterial cannula is comparable to the predicate device in intended use and other labeling, fundamental scientific technology, material type, principles of operation and functional performance evaluations.

Functional/Safety Testing: The functional data indicate that the proposed device performs in a substantially equivalent manner when compared with the predicate device.

Conclusion:
The EndoDirect arterial cannula is substantially equivalent to the cited predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JAN 14 2010

Edwards Lifesciences, LLC
c/o Spencer Walker
Regulatory Affairs Associate II
6864 South 300 West
Midvale, UT 84047

Re: K093730
Edwards Lifesciences EndoDirect Arterial Cannula – ED24
Regulation Number: 21 CFR 870.4210
Regulation Name: Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass
Regulatory Class: Class II
Product Code: DWF
Dated: December 2, 2009
Received: December 3, 2009

Dear Mr. Walker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K093730

Device Name: PORT ACCESS Systems EndoDirect Arterial Cannula

Indications for Use:

The EndoDirect arterial cannula is indicated for patients undergoing cardiopulmonary bypass. The cannula is intended to deliver oxygenated blood for cardiopulmonary bypass for a duration of less than 6 hours. The EndoDirect arterial cannula also allows the hemostatic introduction and removal of vascular catheters such as the Port Access EndoClamp aortic catheter. The EndoDirect arterial cannula is intended for introduction and use through a thoracic trocar or incision.

The AutoIncisor Introducer is intended for use with Port Access arterial cannulae. It is intended for incising the aorta and introducing the cannula into the aorta.

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Kochman

(Division Sign-Off)
Division of Cardiovascular Devices

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